AN ITALIAN COMPANY THAT RESEARCHES, DEVELOPS AND PRODUCES READY TO USE KITS
USING CHROMATOGRAPHIC TECHNIQUES FOR CLINICAL LABORATORIES

CONTROL LYOPHIL. IN URINE FOR DRUGS OF ABUSE – LEVELS 1 and 2

(EDDP, 6-MAM, Cocaine)

Code CC48019

OBJECTIVE

These controls in urine are used for internal quality control and serve to keep under control the accuracy and precision of the analytical procedures dedicated to the quantitative determination of the analytes contained therein. These controls are lyophilized in human matrix and are available in two different concentration range.

RECONSTITUTION

Remove the metal seal and rubber stopper from the vial. Add exactly 5 ml of HPLC grade H_2O in the vial. Replace the rubber stopper, shake and let stand for 5 to 10 minutes. Before use, mix by inverting the vial to dissolve the material until a homogeneous clear solution.

STORAGE AND STABILITY

The controls are stable for 36 months from the date of preparation if stored at 2-8 ° C. After reconstitution are stable 2 days at 2-8 ° C and 2 months at -20 ° C. Do not use after the expiry date.

PRECAUTIONS

These controls in human matrix should be treated with care and treated as potentially infectious.

PACKAGING AVAILABLE:

- CC48019 CONTROL IN URINE FOR EDDP, 6-MAM and COCAINE - LEVELS 1 and 2 ***2 x 6 x 5 ml***

N° 004	**06/2024**

CONCENTRATIONS
COD. CC48019

ANALYTE	*MEASUREMENT UNIT*	*MEDIUM VALUE L1*	*RANGE L1*	*OBTAINED MEDIUM L1 VALUE ± DS**	*MEDIUM VALUE L1*	*RANGE L1*	*OBTAINED MEDIUM L2 VALUE ± DS**
EDDP	**ng/ml**						
6-MAM	**ng/ml**						
COCAINE	**ng/ml**						

* The procedures for production and validation / quality control of every batch shall be performed using the chromatographic method LC / MS / MS validated according to international guidelines of the Food and Drug Administration (FDA-May 2001) and the International Conference of Harmonisation of technical requirements for registration of pharmaceuticals for human use (ICH-Q2-R1-Nov 2005). The mean value and standard deviation were obtained during the validation phase of batch processing for level four bottles in duplicate.

This product fulfils all the requirements of Directive 98/79/EC of 27/10/1998 on *in vitro* diagnostic medical devices (IVD). The declaration of conformity is available upon request.

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FOR *IN VITRO* DIAGNOSTIC USE ONLY

EUREKA S.R.L. LAB DIVISION
Via M. D'Antona 28
60033 Chiaravalle (AN) - Italy
Tel +39 071 7450790
eureka-support@sentinel.it
www.eurekakit.com